

AMENDMENT AND RESPONSE UNDER 37 C.F.R § 1.116

Serial Number: 10/572,502

Filing Date: March 17, 2006

Title: ORAL DRUG DELIVERY SYSTEM

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IN THE CLAIMS

Please replace the previous set of claims with the following amended set of claims.

1-24. (Cancelled)

25. (Currently Amended) An orally administerable administerable drug delivery system having at least one outer surface, the said system comprising:

(1) a core comprising [[an]] one or more active ingredient composition region regions and a separate swellable or reactive composition region,

(i) the one or more active ingredient composition region regions comprising at least one pharmaceutically active ingredient and [[a]] one or more pharmaceutically acceptable excipient excipients, wherein in at least one active ingredient composition region, at least one pharmaceutically acceptable excipient is a rate controlling excipient, and

(ii) the swellable or reactive composition region comprising one or both of a swellable or a reactive composition; and

(2) a water-insoluble polymer coating surrounding the core;

wherein the swellable or the reactive composition region is located in an immediate vicinity of one or more preselected portions of the coating in order to be in communication with said preselected portions of the coating[[;]], and the one or more active ingredient composition [[is]]regions are in the vicinity of another portion of the coating;

wherein at least one preselected portion of the coating is operable to be removed after contact with an aqueous environment and wherein the remaining portion of the coating is not operable to be removed.

26. (Previously Presented) The orally administerable drug delivery system as claimed in claim 25, wherein the coating is selected from defective coatings or reactive coatings.

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27. **(Previously Presented)** The orally administerable drug delivery system as claimed in claim 26, wherein the defective coating comprises one or more passageways on the preselected portions of the coating.

28. **(Currently Amended)** The orally administerable drug delivery system as claimed in claim 27 any one of claims 25, 26, or 27, wherein the coating is impermeable to the pharmaceutically active ingredient.

29. **(Currently Amended)** The orally administerable drug delivery system as claimed in claim 25, any one of claims 25, 26, or 27, wherein the coating is semipermeable.

30. **(Currently Amended)** The orally administerable drug delivery system as claimed in claim 25, wherein the one or more active ingredient composition is present as regions are in the form of one or more layers and the swellable composition region is present as in the form of one or more layers.

31. **(Currently Amended)** The orally administerable drug delivery system as claimed in claim 30, wherein the active ingredient in any one of the active ingredient composition layers may be present in the one or more layers is the same or different from the active ingredient in any of the other active ingredient composition layers.

32. **(Cancelled)**

33. **(Cancelled)**

34. **(Previously Presented)** The orally administerable drug delivery system as claimed in claim 25, wherein the swellable composition comprises a swelling agent.

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35. **(Previously Presented)** The orally administerable drug delivery system as claimed in claim 34, wherein the swelling agent is selected from a swellable excipient, a gas generating agent, or mixtures thereof.

36. **(Previously Presented)** The orally administerable drug delivery system as claimed in claim 25, wherein the swellable composition comprises one or more wicking agents.

37. **(Previously Presented)** The orally administerable drug delivery system as claimed in claim 25, wherein the swellable composition comprises one or more osmogents.

38. **(Currently Amended)** The orally administerable drug delivery system as claimed in claim 25, wherein the active ingredient ~~composition~~ is released without a substantial delay after the tablet contacts the aqueous environment.

39. **(Currently Amended)** The orally administerable drug delivery system as claimed in claim 25, further comprising ~~a second an~~ outer coating including a pH-dependent polymer.

40. **(Previously Presented)** The orally administerable drug delivery system of claim 25, wherein the swellable or reactive composition region is in the form of an in-lay.

41. **(Cancelled)**

42. **(Currently Amended)** An orally ~~administerable~~ administerable drug delivery system having at least one outer surface, the said system is in the form of a multilayer coated tablet, comprising:

(1) a core comprising at least two layers, at least one layer consisting of an active ingredient composition and at least one a layer consisting of a swellable or reactive composition;

(i) the at least one active ingredient composition layer comprising at least one a pharmaceutically active ingredient and [[a]] at least one pharmaceutically

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acceptable excipient, wherein in at least one active ingredient composition layer
the at least one pharmaceutically acceptable excipient is a rate controlling
excipient, and

- (ii) the swellable or reactive composition layer comprising one or both of a
swellable or a reactive composition; and

- (2) a water-insoluble polymer coating surrounding the core;

wherein the at least one swellable or [[the]] reactive composition layer is located in an
immediate vicinity of one or more preselected portions of the coating in order to be in
communication with said preselected portions of the coating; and the at least one active
ingredient composition layer is in vicinity of another portion of the coating; and

wherein at least one preselected portion of the coating is operable to be removed after
contact with an aqueous environment and wherein the remaining portion of the coating is not
operable to be removed.